

Cancer Trials Ireland CLG

Directors' Report and Financial Statements
for the financial year ended
31 December 2018

Registered Number: 268044

CANCER TRIALS IRELAND CLG

**DIRECTORS' REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

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CANCER TRIALS IRELAND CLG

DIRECTORS AND OTHER INFORMATION

DIRECTORS

Dr. Jonathan Westrup (Chairman)
Darren Byrne
Dr. Linda Coate (Appointed 17th May 2018)
Dr. Jerome Coffey
Dr. Leisha Daly
Berchmans Gannon
Diane Hanly (appointed 8th November 2018)
Prof. Bryan Hennessy
Dr. Cathy Kelly (Resigned 17th May 2018)
Dr. Paul Kelly
Prof. Ray McDermott
Prof. Patrick Murray (Resigned 17th May 2018)
Dr. Robert O'Connor
Evelyn O'Rourke

COMPANY SECRETARY

Mr. Robert Cosgrave

**REGISTERED OFFICE
AND BUSINESS ADDRESS**

Innovation House
Old Finglas Road
Glasnevin
Dublin 11

COMPANY NUMBER

268044

CHY NUMBER

12492

CRA NUMBER

20036676

INDEPENDENT AUDITORS

Deloitte Ireland LLP
Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House
Earlsfort Terrace
Dublin 2

SOLICITORS

Eversheds Solicitors
One Earlsfort Centre
Earlsfort Terrace
Dublin 2

Hayes Solicitors
Lavery House
Earlsfort Terrace
Dublin 2

BANKERS

AIB Bank plc
Unit 33 Blackthorn Road
Sandyford
Dublin 18

KBC Bank Ireland plc
Sandwith Street
Dublin 2

Permanent TSB
2/4 Upper Baggot Street
Dublin 4

CANCER TRIALS IRELAND CLG

DIRECTORS' REPORT FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

The Directors present their annual report, together with the audited financial statements, for the financial year ended 31 December 2018.

PRINCIPAL ACTIVITY AND REVIEW OF THE ORGANISATION

Since Cancer Trials Ireland was established in 1996, more than 15,000 patients have participated in over 350 of its trials.

Almost all cancer treating specialists in Ireland are members of Cancer Trials Ireland.

The trials are carried out in 14 hospital based Cancer Trials Units (CTUs) across the country that are supported by a central team of clinical researchers, project managers, data managers and other experts.

As well as managing its own in-house academic trials, Cancer Trials Ireland also works with global pharmaceutical companies and international collaborative research groups from around the world which generates substantial inward investment and access to innovative treatments for cancer patients.

Cancer is a global health issue.

In 2012, there were 14.1 million new cancer cases and 8.2 million cancer-related deaths worldwide.

Incidences of cancer in Ireland reflect what is happening globally. The number of new cases of invasive cancer cases (including non-melanoma skin cancer) is expected to increase by between 86% and 125% for females and by between 126% and 133% for males between 2010 and 2040.

In Ireland the Department of Health's 2015-2017 Statement of Strategy notes that the incidences of cancer are projected to double by 2040. It states that *"a key task in the coming years will be to work to prevent cancer occurring in the first place as far as possible and to tackle cancer early when it does occur"*.

Reflecting this commitment, the key elements of the 3rd National Cancer Strategy developed in 2016 include the KPI to double the number of patients on drug trials from 3% to 6% by 2020.

OBSERVATIONS AND ACTIVITIES

During 2018, in the 14 hospital-based research units, Cancer Trials Ireland were working on 81 trials actively recruiting patients and involving approximately 6,000 patients with an additional 4,000 patients enrolled onto patient registry studies. All the trials involved the staff at Cancer Trials Ireland General Central Office.

In 2018, approximately, 20% of the trials are in-house academic trials (2017: 20%) funded by the grants received from the Health Research Board and the Irish Cancer Society. The other 41% (2017: 34%) of these trials involved collaboration with cancer research groups and/or Investigator Initiated Studies which are funded through pharmaceutical companies. The balance of our portfolio is 39% (2017: 46%) and are trials run by international pharmaceutical companies in Irish hospitals where staff at the General Central Office do limited work and receive no support. However, for a complete picture we adopt them to our portfolio.

In 2018 accrual on Cancer Trials Ireland studies was 348 patients on clinical trials and 654 patients on translational studies.

The work of Cancer Trials Ireland and the associated research teams and their leadership around the country is critically important for people with cancer. Following an organisational review completed in 2014, Cancer Trials Ireland embarked on an important strategic change programme to enable it to move from operating as a small organisation to a medium-sized clinical trials group.

CANCER TRIALS IRELAND CLG

DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

VISION AND MISSION

The vision at Cancer Trials Ireland is focused on one primary purpose. To provide every patient with cancer with access to high-quality and potentially life altering cancer trial and make Ireland a highly attractive location to open cancer trials. Our mission is to discover new diagnostics and treatments that will extend and enhance the lives of the millions of people who are diagnosed with cancer each year.

In order to achieve this vision, Cancer Trials Ireland must undertake translational and clinical cancer trials which investigate all disease areas and it must have in place the organisational capability to do so.

The 5 strategic pillars are the key to enable Cancer Trials Ireland to achieve this vision and mission:

1. Governance
2. Profile
3. Funding Model
4. Operational Capabilities
5. Clinical Capabilities

STRUCTURE, GOVERNANCE AND MANAGEMENT

The Board rotates at the AGM every year as per the Constitution. The Board is chaired by Dr. Jonathan Westrup, appointed in 2014 and he is a strategy and governance expert. The Board meets 5 times per year and permanent agenda items include reports from Clinical Executive Committee and Audit Committee, Governance, Strategy, Conflict of Interest Declarations and Finance. In 2018, the Board met 5 times and had 2 additional special Board meetings. The Board met 5 times in 2017. (2017: 5)

The members of the Board are qualified to hold their position and represent a range of skills; governance, patient advocate, clinical oncologists, radiation oncologists, industry representative, finance and National Cancer and Control Programme (NCCP) representative. In 2018 the Board appointed a new subgroup called the Patient Consultant's Committee (PCC) set up to integrate the patient voice and experience in the governance structure of the organization. Diane Hanly is the Chair of the PCC and was elected to the Board at the AGM in 2018.

The Clinical Executive Committee (CEC), Scientific Management Group and Disease Specific SubGroups monitor progress on the ongoing clinical trials, make decisions on the adoption of new trials to the portfolio and the CEC reports to the Board of Directors through its Chair; Prof. Bryan Hennessy, Clinical Lead.

The Audit Committee is a subcommittee of the Board and was established in the summer of 2016 and met 3 times in 2018 (2017:4) Darren Byrne is the chair of the Audit Committee and member of the Board of Directors.

OUR BOARD OF DIRECTORS

A number of directors are Clinical Leads, Principal Investigators or involved in collaborative studies with the company ("Cancer Trials Ireland"). All trials and research studies were approved in the normal course of business. The directors have no financial beneficial interest in the research, nor did they receive remuneration for their contribution to this research. Details of the directors and their contribution to the company are outlined below:

Dr. Jonathan Westrup, Chair

Dr. Jonathan Westrup is a partner of Acorn Governance Solutions and a company director.

Berchmans Gannon

Legal Expert, formerly Beauchamps Solicitors.

CANCER TRIALS IRELAND CLG

DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

OUR BOARD OF DIRECTORS (CONTINUED)

Prof. Bryan Hennessy, Clinical Lead

Consultant Medical Oncologist in Beaumont Hospital, Dublin, and Our Lady of Lourdes Hospital, Drogheda, Lecturer at Royal College of Surgeons in Ireland (RCSI), an Adjunct Professor in the Division of Cancer Medicine at MD Anderson Cancer Centre (MDACC). Cancer Trials Ireland protects Prof. Hennessy's time through funding the RCSI where his research work is carried out, this funding is used to resource the department to employ a researcher so that Prof. Hennessy can carry out his duties as Cancer Trials Ireland Clinical Lead.

Prof. Cathy Kelly

Consultant Medical Oncologist at the Mater Misericordiae University Hospital, Dublin. Prof. Kelly is an investigator on a number of trials in the Cancer Trials Ireland portfolio.

Darren Byrne, Chair of Audit Committee

Commercial Experienced Chartered Accountant / CFO and Non-Executive Director.

Evelyn O'Rourke, Patient Advocate

Radio and Television Broadcaster with RTÉ.

Dr. Jerome Coffey

Director of the National Cancer Control Programme (NCCP). The NCCP are tasked with the responsibility of implementing the next Cancer Strategy where there are key performance indicators for clinical trials.

Dr. Leisha Daly

Dr Leisha Daly is Senior Director Government Affairs, Supply Chain EMEA & J&J Ireland at Johnson & Johnson since September 2018. She was previously Country Director of Janssen and was a director of the Irish Pharmaceutical Healthcare Association up to September 2018. She has been a director of Janssen Sciences Ireland (Unlimited) Company since April 2017. Dr Daly is not a member of the Board of Directors of Janssen who are involved in some collaborative studies with Cancer Trials Ireland Investigators.

Dr. Linda Coate

Consultant Medical Oncologist, University Hospital Limerick.

Diane Hanly

Chair of the Patient Consultant's Committee.

Prof. Patrick Murray

Professor of Clinical Pharmacology in University College Dublin, and a consultant physician (clinical pharmacologist & nephrologist) at the Mater Misericordiae University Hospital, Dublin.

Dr. Paul Kelly

Consultant Radiation Oncologist at Cork University Hospital. Dr. Kelly is an investigator on a number of trials in the Cancer Trials Ireland portfolio.

Prof. Ray McDermott

Consultant Medical Oncologist at the Adelaide Meath & National Children's Hospital, Tallaght, and St Vincent's University Hospital, Dublin. Prof. McDermott is an investigator on a number of trials in the Cancer Trials Ireland portfolio.

Dr. Robert O'Connor

Head of Research at the Irish Cancer Society. The Irish Cancer Society award a grant to Cancer Trials Ireland every year. Dr. O'Connor is not a member the Board of the Irish Cancer Society.

CANCER TRIALS IRELAND CLG

DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

OUR BOARD OF DIRECTORS (CONTINUED)

DIRECTORS AND SECRETARY

The directors and secretary who served throughout the year, except as noted, were as follows:

Directors:

Dr. Jonathan Westrup (Chairman)
Darren Byrne
Dr. Linda Coate (Appointed 17th May 2018)
Dr. Jerome Coffey
Dr. Leisha Daly
Berchmans Gannon
Diane Hanly (appointed 8th November 2018)
Prof. Bryan Hennessy
Dr. Cathy Kelly (Resigned 17th May 2018)
Dr. Paul Kelly
Prof. Ray McDermott
Prof. Patrick Murray (Resigned 17th May 2018)
Dr. Robert O'Connor
Evelyn O'Rourke

Secretary:

Mr. Robert Cosgrave

In accordance with the Constitution, the longest serving directors must retire each year but may offer themselves for re-election.

ACHIEVEMENTS AND PERFORMANCE

- The Health Research Board conducted an external scientific panel review of the work of Cancer Trials Ireland in 2018. The report from the panel was very positive about the work of the group and has informed the decision to award a 4 year grant (2021-24) including the Data and Statistics function to Cancer Trials Ireland. The award will be subject to the usual considerations.
- Cancer Trials Ireland ran the third successful externally funded Just Ask Your Doctor public information campaign communicating with the public and members on radio and media interviews on the value of cancer trials.
- Cancer Trials Ireland advocacy activities in 2018 included making representations to the Department of Health, NCCP and the Minister for Health's office;
- A group of volunteers came together to offer their support to Cancer Trials Ireland and an inaugural lunch to raise awareness and funds to help Cancer Trials Ireland's important work was held. Some of the volunteers are related to Directors of the company and others are people with an interest in our mission to do more clinical trials for people with cancer. Patients who took part in some of our trials were represented by friends and family and were the biggest supporters at the event. The success of the event is an incredible testament to the work of the team at Cancer Trials Ireland.
- Cancer Trials Ireland facilitated regular Stakeholder Engagement and Patient Advocate Advisory Group (PAAG) meetings in 2018 including working with partners in the Northern Ireland Cancer Trials Network on sharing ideas on trials and exchanging learnings on patient involvement in research.

FINANCIAL REVIEW

Cancer Trials Ireland is funded by grants from the Health Research Board, the Irish Cancer Society and St Luke's Institute of Cancer Research. The organisation also receives contributions towards costs for work done with international collaborative groups and from pharmaceutical companies for our own in-house Investigator Initiated Studies. Cancer Trials Ireland do not fundraise but from time to time individuals and groups of friends organise to donate to the work of the group.

The Finance Team reporting to the Audit Committee continue to update where necessary, all relevant finance policies and procedures.

CANCER TRIALS IRELAND CLG

DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

STATEMENT OF RISK MANAGEMENT

Clinical trials can take up to 25 years to complete with the first 5 years being the most resource intensive period. In-house trials, trials which are initiated and led by Cancer Trial Ireland investigators, depend on grants from the HRB and Irish Cancer Society and funding from pharmaceutical companies which, due to the nature of trials, are spread over many years. As a result of the long lifecycle of trials the 20% cut to Cancer Trials Ireland's 2016-2018 HRB grant presented particular challenges. As trials cannot (for ethical and regulatory reasons) be stopped mid-way through their cycle for funding reasons, the shortfall that resulted from these grant cuts had to be covered from the organisation's reserves. This illustrates the risks associated with short term funding cycles.

During 2018, Cancer Trials Ireland continue to implement decisions made by the Scientific Management Group (SMG) for new academic studies. The SMG have had to decline opening new trials in 2018 with important research questions because we cannot cover all the costs. In this year, due to reduced funding and pressure to maintain regulatory obligations, the management made the decision to reduce spend on overhead-related staff resource.

While we are challenged to open new in-house trials, we are continuing to do more trials in partnership with international collaborative groups. These trials cover costs and offer patients new treatment options. In addition, our clinicians continue to craft new research ideas and propose their studies to new partners and while some external partners can provide financial support to Cancer Trials Ireland, they cannot cover all the costs involved in sponsoring a clinical trial particularly a drug trial which is highly regulated. This is a common concern for Academic Clinical Trials Groups in Europe. The risk is academic groups like ours continue to lack ring-fenced core support, ideally from the State to enable our team at Cancer Trials Ireland to do the work and ask research questions relevant to the needs of patients.

PLANS FOR FUTURE PERIOD

The HRB International Scientific Panel Review took place in 2018 and the report has led to a 6-year commitment from the Health Research Board to Cancer Trials Ireland. While the funding cut has not been reversed in 2018 and 2019, there has been an overhead allocation for the General Central Office (GCO) in 2019. The % allocation of grant to the GCO and Hospital Sites in the 2021-24 grant has to be discussed but there is support for bringing stability to Cancer Trials Ireland GCO and opening up more academic trials.

Implementing a successful cancer trials portfolio involves engaging and collaborating with numerous stakeholders at both a national and global level. As part of the change programme, Cancer Trials Ireland has strengthened and continues to strengthen its relationship with external organisations. The aim is to be even more connected with stakeholders such as the HRB, Irish Cancer Society, National Cancer Control Programme (NCCP), Department of Health, the Clinical Research Facility Galway (CRFG), international collaborative groups, pharmaceutical companies, and other stakeholders such as the wider cancer research community, cancer patients and the public where possible.

The organisation will continue to act as an advocate for cancer trials and highlight its contribution not only in terms of fighting the battle against cancer but also its economic contribution.

GOING CONCERN

The directors have a reasonable expectation that the company has adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis on preparing the financial statements. Further details regarding the adoption of the going concern basis can be found in Note 2 to the financial statements.

CANCER TRIALS IRELAND CLG

**DIRECTORS' REPORT (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

POST BALANCE SHEET EVENTS

There have been no circumstances or events subsequent to the financial year end, which would require adjustment to or disclosure in the financial statements or in the notes thereto.

ACCOUNTING RECORDS

The measures taken by the directors to ensure compliance with the requirements of Section 281 to 285 of the Companies Act 2014 with regards to keeping of accounting records, are the employment of appropriately qualified accounting personnel and the maintenance of computerised accounting systems. The company's accounting records are maintained at Innovation House, Old Finglas Road, Glasnevin, Dublin 11.

DISCLOSURE OF INFORMATION TO AUDITORS

In the case of each of the persons who are directors at the time the directors' report and financial statements are approved:

- a) So far as the director is aware, there is no relevant audit information of which the company's statutory auditors are unaware; and
- b) Each director has taken all steps that ought to have been taken by the director in order to make himself or herself aware of any relevant audit information and to establish that the company's auditors are aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Companies Act 2014 (as amended).

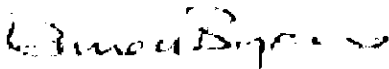
AUDITORS

The auditors, Deloitte Ireland LLP, Chartered Accountants and Statutory Audit Firm, continue in office in accordance with the provisions of Section 383(2) of the Companies Act, 2014.

Approved by the Board and signed on its behalf by:



Berchmans Gannon
Director



Darren Byrne
Director

Date: 6th August 2019

CANCER TRIALS IRELAND CLG

DIRECTORS' RESPONSIBILITIES STATEMENT

The directors are responsible for preparing the directors' report and the financial statements in accordance with the Companies Act 2014.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* issued by the Financial Reporting Council ("relevant financial reporting framework"). Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the company as at the financial year end date and of the profit or loss of the company for the financial year and otherwise comply with the Companies Act 2014.

In preparing those financial statements, the directors are required to:

- select suitable accounting policies for the Company Financial Statements and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company, enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy, enable them to ensure that the financial statements and directors' report comply with the Companies Act 2014 and enable the financial statements to be audited.

They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities

Independent auditor's report to the members of Cancer Trials Ireland CLG

Report on the audit of the financial statements

Opinion on the financial statements of Cancer Trials Ireland CLG (the 'company')

In our opinion the financial statements:

- give a true and fair view of the assets, liabilities and financial position of the company as at 31 December 2018 and of the surplus for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Statement of Income and Retained Earnings;
- the Balance Sheet;
- the Statement of Cash Flows; and
- the related notes 1 to 18, including a summary of significant accounting policies as set out in note 2.

The relevant financial reporting framework that has been applied in their preparation is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" issued by the Financial Reporting Council ("the relevant financial reporting framework").

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "Auditor's responsibilities for the audit of the financial statements" section of our report.

We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors' use of the going concern basis of accounting in preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

Other information

The directors are responsible for the other information. The other information comprises the information included in the Directors' Report and Financial Statements for the financial year ended 31 December 2018, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

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Independent auditor's report to the members of Cancer Trials Ireland CLG

Other information (Continued)

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Responsibilities of directors

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity (or where relevant, the group) to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

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Independent auditor's report to the members of Cancer Trials Ireland CLG

Auditor's responsibilities for the audit of the financial statements (Continued)

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Report on other legal and regulatory requirements

Opinion on other matters prescribed by the Companies Act 2014

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the financial statements to be readily and properly audited.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

Matters on which we are required to report by exception

Based on the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.



Margarita Martin
For and on behalf of Deloitte Ireland LLP
Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House, Earlsfort Terrace, Dublin 2

Date: 6 August 2019

CANCER TRIALS IRELAND CLG

**STATEMENT OF INCOME AND RETAINED EARNINGS
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

	<i>Notes</i>	2018 €	2017 €
Income	<i>4</i>	3,543,126	3,570,106
Expenditure		(3,442,452)	(3,948,115)
Surplus/ (Deficit) on ordinary activities before interest		100,674	(378,009)
Interest receivable and similar income	<i>5</i>	4,198	9,815
SURPLUS/ (DEFICIT) FOR THE FINANCIAL YEAR	<i>6</i>	104,872	(368,194)
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR		293,732	661,926
RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR		398,604	293,732

Income and expenditure are all derived from continuing operations.

CANCER TRIALS IRELAND CLG

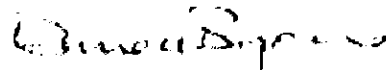
BALANCE SHEET AS AT 31 DECEMBER 2018

	Notes	2018 €	2017 €
Fixed Assets			
Tangible assets	10	14,183	25,426
Current Assets			
Debtors	11	1,463,076	1,849,389
Cash and cash equivalents		2,870,645	2,917,040
		4,333,721	4,766,429
Creditors: Amounts falling due within one year	12	(3,949,300)	(4,498,123)
Net Current Assets		384,421	268,306
Net Assets		398,604	293,732
Reserves			
Retained earnings		398,604	293,732
		398,604	293,732

The financial statements were approved and authorised for issue by the Board of Directors on 6th AUGUST 2019 and signed on its behalf by:



Berchmans Gannon
Director



Darren Byrne
Director

CANCER TRIALS IRELAND CLG

STATEMENT OF CASH FLOWS
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

Reconciliation of surplus/(deficit) for the financial year to net cash flows from operating activities	<i>Notes</i>	2018	2017
		€	€
Surplus/ (deficit) for the financial year		104,872	(368,194)
Adjustments for:			
Interest receivable and similar income	5	(4,198)	(9,815)
Depreciation	10	14,746	23,489
Loss on disposal of fixed assets	10	280	4,166
Operating cash flows before movements in working capital		115,700	(350,354)
Decrease/ (increase) in debtors		386,313	(652,880)
Decrease in creditors		(548,823)	(642,287)
Net cash flows from operating activities		(46,810)	(1,645,521)
Cash flows from investing activities			
Interest received	5	4,198	9,815
Payments to acquire tangible fixed assets	10	(3,783)	(17,826)
Net cash flows from investing activities		415	(8,011)
Net decrease in cash and cash equivalents		(46,395)	(1,653,532)
Cash and cash equivalents at beginning of financial year		2,917,040	4,570,572
Cash and cash equivalents at end of financial year		2,870,645	2,917,040

CANCER TRIALS IRELAND CLG

NOTES TO THE FINANCIAL STATEMENTS FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

1. GENERAL INFORMATION

Cancer Trials Ireland CLG (Registered number 268044) is a company limited by guarantee incorporated in the Republic of Ireland under Companies Act 2014. The address of the registered office and principal place of business is Innovation House, Old Finglas Road, Glasnevin, Dublin 11. The nature of the company's operations and its principal activities are set out in the Directors' Report on pages 3 to 8. The financial statements have been presented in Euro (€) which is also the functional currency of the company.

The change of company name was formally registered with the Companies Registration Office on 15 March 2018.

2. ACCOUNTING POLICIES

The significant accounting policies adopted by the company are summarised below. The accounting policies and measurement bases have all been applied consistently throughout the current and the preceding financial year.

Statement of compliance

The financial statements of the company for the year ended 31 December 2018 have been prepared on the going concern basis and in accordance with FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" (FRS 102).

Basis of preparation

The financial statements have been prepared on the going concern basis and in accordance with the historical cost convention. Historical cost is generally based on the fair value of the consideration given in exchange for assets. The financial reporting framework that has been applied in their preparation is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" issued by the Financial Reporting Council.

Income

In respect of research trials, when the outcome of a research contract cannot be estimated reliably, the company recognises revenue only to the extent of contract costs incurred that it is probable will be recovered, and the company recognises costs as an expense in the period in which they are incurred.

When it is probable that total research contract costs will exceed total contract revenue, the expected loss is recognised by the company immediately, with a corresponding provision for an onerous contract.

Grant income is recognised in the period in which there is entitlement, certainty of receipt and the amount can be measured with sufficient reliability. Income received relating to expense reimbursements is recorded once the claim has been agreed and the amount has been received. Income is deferred when monies are received in advance of the expenditure on the trials to which they relate.

Public donations and similar income arising from fundraising events are accounted for when received. As with many similar charitable organisations, independent groups from time to time organise fundraising activities. However, as amounts collected in this way are outside the control of the company, they are not included in the financial statements until received by the company.

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

2. ACCOUNTING POLICIES (CONTINUED)

Pensions

The company operates a defined contribution pension scheme. Pension contributions in respect of the scheme for employees, are charged to the income and expenditure account as they become payable in accordance with the rules of the scheme. The assets are held separately from those of the company in an independently administered fund. Differences between the amounts charged in the income and expenditure account and payments made to pension funds are treated as assets or liabilities.

Taxation

The company is a registered charity and no provision is considered necessary for taxation.

Tangible fixed assets and depreciation

Tangible fixed assets are stated at cost or at valuation, less accumulated depreciation. The charge to depreciation is calculated to write off the original cost or valuation of tangible fixed assets, less the estimated residual value, over their expected useful lives as follows:

Fixtures, fittings and equipment	-	15% Straight Line
Computer equipment	-	33% Straight Line

The carrying values of tangible fixed assets are reviewed annually for impairment in periods if events or changes in circumstances indicate the carrying value may not be recoverable.

Foreign currencies

Monetary assets and liabilities denominated in foreign currencies are translated at the rates of exchange ruling at the Balance Sheet date. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated at the rates of exchange ruling at the date of the transaction. Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. The resulting exchange differences are dealt with in the Income and Expenditure Account.

Going Concern

The company's business activities, together with the factors likely to affect its future development, performance and position are set out in the directors' report. The directors' report describes the financial position of the company; its cash flows, liquidity position; the company's objectives, policies and processes for managing its capital; its financial risk management objectives. The company meets its day to day working capital requirements through accumulated reserves and cash in bank balances. The directors have a reasonable expectation that the company has adequate resources to continue in operational existence for the foreseeable future. Thus they continue to adopt the going concern basis of accounting in preparing the annual financial statements.

2. ACCOUNTING POLICIES (CONTINUED)

Financial instruments

Financial assets and financial liabilities are recognised when the company becomes a party to the contractual provisions of the instrument. Financial liabilities are classified according to the substance of the contractual arrangements entered into. An equity instrument is any contract that evidences a residual interest in the assets of the company after deducting all of its liabilities.

The financial instruments are recognised and measured in accordance with Section 11 and Section 12 of FRS 102.

Financial assets and liabilities

All financial assets and liabilities are initially measured at transaction price (including transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a finance transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument. Financial assets and liabilities are only offset in the balance sheet when, and only when there exists a legally enforceable right to set off the recognised amounts and the company intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Financial assets are derecognised when and only when a) the contractual rights to the cash flows from the financial asset expire or are settled, b) the company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or c) the company, despite having retained some significant risks and rewards of ownership, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer.

Financial liabilities are derecognised only when the obligation specified in the contract is discharged, cancelled or expires. Balances that are classified as payable or receivable within one financial year on initial recognition are measured at the undiscounted amount of the cash or other consideration expected to be paid or received, net of impairment.

Leases

Rentals under operating leases are charged on a straight-line basis over the lease term, even if the payments are not made on such a basis.

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

3. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of the Company's accounting policies, which are described in note 2, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

In the opinion of the directors, there were no critical judgements, apart from those involving estimations (which are dealt with separately below), made in the process of applying the company's accounting policies. The directors have assessed the going concern basis for the preparation of the financial statements which is detailed in note 2.

Key source of estimation on uncertainty - Revenue recognition of research contracts

In respect of research trials, the directors assess the probable recoverability of research contract costs incurred. In addition if it is probable that total research contract costs will exceed total research contract revenue, the directors consider the value of such expected losses and recognise the provision under an onerous contract.

4. INCOME

The company's income is attributable to cancer research grants, clinical trials income and philanthropic contributions. All activities are carried out in the Republic of Ireland.

	2018	2017
	€	€
Grants	1,840,593	1,710,468
Study income	1,420,364	1,770,305
Donations and Fundraising	282,169	89,333
	3,543,126	3,570,106

5. INTEREST RECEIVABLE AND SIMILAR INCOME

	2018	2017
	€	€
Bank interest	4,198	9,815

6. SURPLUS/ (DEFICIT) FOR THE FINANCIAL YEAR

	2018	2017
	€	€
Surplus/ (deficit) for the financial year is stated after charging:		
Depreciation of tangible fixed assets	14,746	23,489
Directors' remuneration	-	-
Auditor's remuneration	18,450	18,488
Loss on disposal of fixed assets	280	4,166

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

7. EMPLOYEES AND REMUNERATION

Number of employees

The average monthly number of persons employed during the financial year was as follows:

	2018 Number	2017 Number
Office and administration	47	51

The staff costs comprise:

	2018 €	2017 €
Wages and salaries	2,147,242	2,378,061
Social insurance costs	231,517	251,411
Other retirement benefit costs	55,644	55,838
Redundancy costs	12,307	12,792
	2,446,710	2,698,102

The number of employees whose salaries (excluding employer pension contributions) were greater than €60,000 were as follows:

	2018 Number	2017 Number
€60,001 - €70,000	6	4
€70,001 - €80,000	3	3
€80,001 - €90,000	2	1
€90,001 - €100,000	1	-
€100,001 - €110,000	1	-
€110,001 - €120,000	-	1

The total remuneration package of the Chief Executive comprised of:

	2018 €	2017 €
Wages and salaries	106,000	106,000
8% employer pension contribution	8,480	8,480
	114,480	114,480

8. KEY MANAGEMENT COMPENSATION

The total remuneration for key management personnel including pension contribution of €22,911 (2017: €22,481) and employer's PRSI of €43,033 (2017: €42,082) for the financial year amounted to €462,561 (2017: €456,822) and this relates to 5 personnel (2017: 5).

CANCER TRIALS IRELAND CLG

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

9. RELATED PARTY TRANSACTIONS

Directors are not paid for any work undertaken on behalf of the company. However, the company's funding contract with the Health Research Board (HRB) allows the company to use hospital funds to pay for substitute staff who enable our Clinical Lead to be released to support our studies. Currently both the Clinical Lead and Vice Clinical Lead are directors of the company.

Our payments to the directors' employers in the current and prior financial year were as follows:

A payment of €107,000 (2017: €107,000) to the Royal College of Surgeons in Ireland (RCSI) in respect of Prof. Bryan Hennessy (Clinical Lead).

In 2017 there was an additional once-off payment of €90,000 made to the Health Services Executive (HSE) in respect of Dr. Linda Coate (Vice Clinical Lead).

10. TANGIBLE FIXED ASSETS

	Fixtures, fittings and equipment €	Computer equipment €	Total €
Cost:			
At 1 January 2018	1,063	273,787	274,850
Additions	1,246	2,537	3,783
Disposals	-	(156,970)	(156,970)
At 31 December 2018	2,309	119,354	121,663
Accumulated Depreciation:			
At 1 January 2018	27	249,397	249,424
Charge for the year	346	14,400	14,746
Disposals	-	(156,690)	(156,690)
At 31 December 2018	373	107,107	107,480
Net book value:			
At 31 December 2018	1,936	12,247	14,183
At 31 December 2017	1,036	24,390	25,426

11. DEBTORS

	2018 €	2017 €
Accrued income	750,248	1,180,568
Trade debtors	691,548	644,390
Prepayments	9,411	12,562
Other debtors	11,869	11,869
	1,463,076	1,849,389

CANCER TRIALS IRELAND CLG

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

12. CREDITORS: Amounts falling due within one year	2018	2017
	€	€
Trade creditors	113,574	143,850
Taxation and social welfare (Note 13)	65,536	65,917
Creditor studies	1,941,124	2,319,636
Other creditors	6,041	228,564
Pension accrual	13,979	10,972
Onerous provision	510,269	454,853
Accruals	73,076	118,626
Deferred income	1,225,701	1,155,705
	3,949,300	4,498,123

13. TAXATION AND SOCIAL WELFARE	2018	2017
	€	€
PAYE/PRSI	65,536	65,917

14. FINANCIAL INSTRUMENTS

The carrying value of the company's financial assets and liabilities are summarised by category below:

	2018	2017
	€	€
Financial assets		
<i>Measured at undiscounted amount receivable</i>		
• Accrued income (note 11)	750,248	1,180,568
• Trade debtors (note 11)	691,548	644,390
• Other debtors (note 11)	11,869	11,869
Financial liabilities		
<i>Measured at undiscounted amount payable</i>		
• Trade creditors (note 12)	113,574	143,850
• Creditor studies (note 12)	1,941,124	2,319,636
• Other creditors (note 12)	6,041	228,564
• Onerous provision (note 12)	510,269	454,853

15. STATUS

The liability of the members is limited.

Every member of the company undertakes to contribute to the assets of the company in the event of it being wound up while they are members or within one year thereafter for the payment of the debts and liabilities of the company contracted before they ceased to be members and the costs, charges and expenses of winding up and for the adjustment of the rights of the contributors among themselves such amount as may be required, not exceeding €1.

CANCER TRIALS IRELAND CLG

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

16. POST BALANCE SHEET EVENTS

There have been no circumstances or events subsequent to the year end, which would require adjustment to or disclosure in the financial statements or in the notes thereto.

17. PENSION COSTS

The company operates an occupational scheme, the assets of which are held by independent managers. The pension charge represents contributions paid or due by the company and amounted to €55,644 (2017: €55,838). There was an amount payable at the financial year end of €13,979 (2017: €10,972).

18. OPERATING LEASE COMMITMENTS

Total future minimum lease payments under non-cancellable operating lease are as follows:

	Buildings 2018 €	Buildings 2017 €
Amount due:		
Within one year	142,440	142,440
Between two and five years	391,710	534,150
After five years	-	-
Total	534,150	676,590

The lease is cancellable by either party by giving 9 months' notice except at the Break Option Date of 1 October 2020, when only two months' notice need be given.